

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 803

[Docket No. 2004N-0527]

DTDM

Display Date	6-14-05
Publication Date	6-15-05
Officer	A. Corbin

Medical Devices; Medical Device Reporting; Confirmation of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule; confirmation of effective date.

4b 7.13.05

70 FR 34652
6.15.05

SUMMARY: The Food and Drug Administration (FDA) is confirming the effective date of July 13, 2005, for the direct final rule that appeared in the **Federal Register** of February 28, 2005 (70 FR 9516). The direct final rule revised the medical device reporting regulations into plain language in order to make the regulations easier to understand. This document confirms the effective date of the direct final rule.

DATES: Effective date confirmed: July 13, 2005.

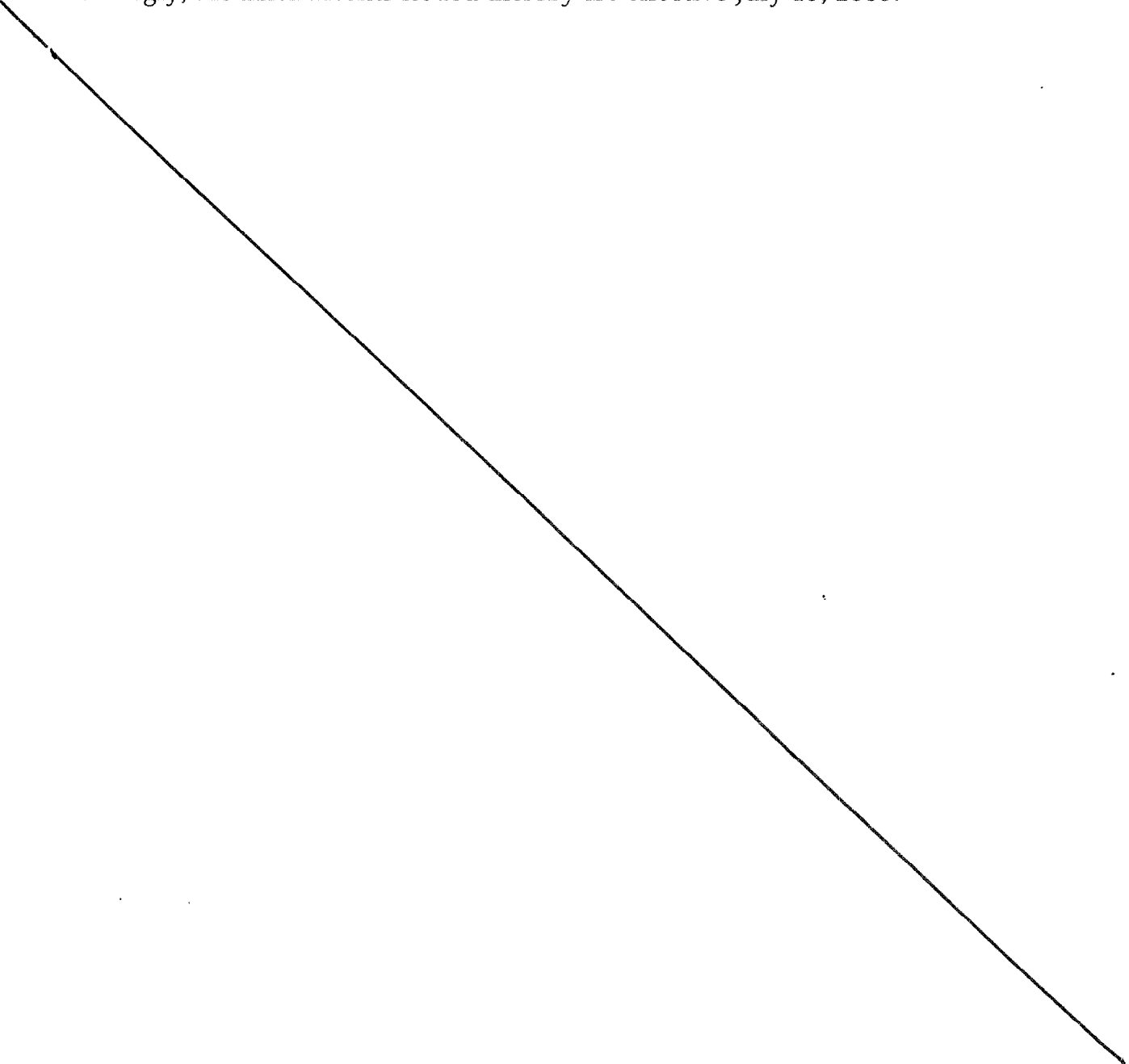
FOR FURTHER INFORMATION CONTACT: Howard Press, Center for Devices and Radiological Health (HFZ-531), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301-827-2983.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of February 28, 2005 (70 FR 9516), FDA solicited comments concerning the direct final rule for a 75-day period ending May 16, 2005. FDA stated that the effective date of the direct final rule would be on July 13, 2005, 60 days after the end of the comment period, unless any significant adverse comment was submitted to FDA during the comment period. FDA received 16 comments, 3 of which supported the plain language revisions and several of which requested further revisions or

substantive changes to the medical device reporting rule. The agency did not receive any significant adverse comment on the plain language revisions.

Authority: Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, notice is given that no objections were filed in response to the February 28, 2005, direct final rule.

Accordingly, the amendments issued thereby are effective July 13, 2005.



Dated: 6/9/05
June 9, 2005.

Jeffrey Shuren

Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 05-????? Filed ??-??-05; 8:45 am]

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